Supplemental Information Disclosure Statement

Applicant acknowledges receipt of a copy of the Forms 1449, which list all the references that were submitted with the Information Disclosure Statement (IDS) filed on November 8, 2001 and the Supplemental Information Disclosure Statements (S-IDS) filed on January 17, 2002, February 26, 2002 and April 30, 2002. However, review of the Form 1449 filed January 17, 2002 reveals that not all the references were marked and initialed as being considered by the Examiner. In particular, PCT publication 00/04004 was not initialed. Applicant respectfully requests that an additional copy of the Form 1449, listing all references that were submitted with the S-IDS filed on January 17, 2002, marked as being considered and initialed by the Examiner, be returned to Applicant's Representative with the next official communication.

REMARKS

Reconsideration and withdrawal of the rejections of the claims in view of the amendments and remarks presented herein is respectfully requested. Claims 1-12, 15 and 18-19 were canceled without prejudice or disclaimer, and solely to advance prosecution of the present application. Claims 20 and 21 are amended in response to the Examiner's comments at page 6 of the Office Action. Claims 13-14, 16-17 and 20-23 are pending in this application.

Objections to the Specification

At page 2 of the office action, the Examiner asserts Compounds **1-4** of Schemes 1 and 2 at pages 42-43 of the specification must be renumbered because they are structurally different from Compounds **1-4** disclosed in Table 1 at page 16 of the specification.

The Examiner is respectfully requested to consider that the compounds appearing in Table 1 of the specification are identified as compounds of formula II (see page 13, page 15, line 25-page 16, line 1), whereas the compounds disclosed at pages 42-43 are not of formula II. Accordingly, the structures of the compounds at pages 42-43 are clearly distinguishable from the structures in Table 1. As a result, one skilled in the art would not be confused by the current numbering scheme. Accordingly, Applicant requests that the Examiner withdraw the objection

to the specification. If the Examiner maintains the objection, Applicant will renumber the compounds and the corresponding text at pages 42-43 in the next response.

The 35 U.S.C. § 112, second paragraph, rejection of the claims

The Examiner rejected claims 20 and 21 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. The Examiner asserts that the claims are indefinite as they lack an essential step, namely, treating the disease. Claims 20-21 have been amended as suggested by the Examiner. Accordingly, withdrawal of the rejection of the claims under 35 U.S.C. §112, second paragraph, is respectfully requested.

For the record it is noted that the original claims 20-21 were directed to "methods of treating." Thus, the instant amendments do not limit the scope of these claims in any way. Accordingly, once allowed, these claims will be entitled to a full scope of equivalents.

The 35 U.S.C. § 112, first paragraph, rejection of the claims

The Examiner rejected claims 13-14, 16-17 and 20-23 under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. As this rejection may be maintained with respect to the pending claims, it is respectfully traversed.

In particular, the Examiner alleges that the present specification does not enable a glycopeptide of formula (II), where R^{20} is $-R^a-W-R^h$ and where W is -S-C(=O)-, a pharmaceutical composition comprising the glycopeptide, and a method of treating a mammal having a bacterial disease by administering the glycopeptide or the pharmaceutical composition comprising the glycopeptide, because the "breath [*sic*] of the claims is broad and encompasses unspecified variants," "there are no working examples demonstrating the claimed variants and methods," and "further experimentation" would be required to prepare the various thioester glycopeptide compounds in the treatment of bacterial diseases (page 4-6 of the Office Action). Therefore, the Examiner alleges that "additional guidance" is required of the specification (pages 5-6 of the Office Action).

The Examiner is respectfully requested to consider that the purpose of the enablement requirement is to assure that the inventor provides sufficient information about the claimed invention so that a person of skill in the field of the invention can make and use it without undue experimentation, relying on the patent specification and the knowledge in the art. Scripps Clinic and Research Foundation v. Genentech, Inc., 927 F.2d 1565, 18 U.S.P.Q. 2d 1001, 18 U.S.P.Q.2d 1896 (Fed. Cir. 1991). The Federal Circuit put forth relevant factors to consider when determining whether experimentation is undue. These factors include: (1) the quantity of experimentation necessary; (2) the amount of direction or guidance presented; (3) the presence or absence of working examples relating to the invention; (4) the nature of the invention; (5) the state of the prior art; (6) the relative skill of those in the art; (7) the predictability or unpredictability of the art; and (8) the breadth of the claims. In re Wands, 8 U.S.P.Q.2d 1400 (Fed. Cir. 1988). Applicant respectfully submits that the claims are fully enabled as discussed below.

Regarding the Examiner's assertion that the claims are overly broad, it is respectfully pointed out that the definition for R^{20} recites only one possibility for the group R^{20}, *viz.*, $-R^a-W-R^h$ where W is -S-C(=O)- (claim 13). In addition, R^a and R^h are clearly defined in the specification. Thus, it is respectfully submitted that this definition of R^{20} is not exceptionally broad, and in light of the discussion below, that the claimed compounds are fully enabled.

It is well-settled that there is no requirement for working examples to fulfill the requirements of 35 U.S.C. §112, first paragraph, if the invention is otherwise disclosed so that one of ordinary skill in the art can practice the invention without undue experimentation. In re Robins, 429 F.2d 452, 166 U.S.P.Q. 552, 555 (C.C.P.A. 1970); In re Borokowski et al., 422 F.2d 904, 164 U.S.P.Q. 642, 645 (C.C.P.A. 1970). Given that there is no statutory requirement for a working example if the disclosure is such that one skilled in the art can practice the claimed invention, and that working examples of related compounds are disclosed in the specification (Examples 1-2), it is respectfully submitted that the present claims are fully enabled.

At page 4 of the Office Action, the Examiner asserts that although the preparation and use of vancomycin and other glycopeptides as antibiotics is disclosed by the prior art, the present specification must provide teachings on the identification and efficacy of various thioester glycopeptide compounds. However, Applicant need not demonstrate the preparation and/or

determine the efficacy of all glycopeptides of formula (II) where R^{20} is $-R^a-W-R^h$ and where W is -S-C(=O)- in order to be entitled to a generic claim of reasonable scope. In re Angstadt, 190 U.S.P.Q. 214 (C.C.P.A. 1976). The scope of the enablement provided by Applicant need only bear a "reasonable correlation" to the scope of the claims. In re Fisher, 166 U.S.P.Q. 18, 24 (C.C.P.A. 1970). The specification provides general schemes (pages 36-43) for the preparation of the claimed glycopeptide compounds. For example, at page 37, lines 1-10, the specification discloses a reductive alkylation method that is useful for appending a group R^a-W-R^h at position R^{20} in formula (II) of claim 13. This information would readily allow one skilled in the art to prepare and use the claimed compounds without undue experimentation. In addition, the present specification discloses that the claimed glycopeptides are highly effective antibacterial agents (page 2, lines 24-26). It is respectfully submitted that the Examiner has not provided any evidence to rebut this assertion.

Furthermore, regarding the allegedly required "further experimentation," the key word is "undue" not "experimentation." In re Angstadt, 537 F.2d 498, 190 U.S.P.Q. 214, 219 (C.C.P.A. 1976). In fact, a considerable amount of experimentation is permissible if it is merely routine, or the specification provides a reasonable amount of guidance with respect to the direction in which the experimentation should take. Ex parte Jackson, 217 U.S.P.Q. 804, 807 (Bd. App. 1982).

The fact that different glycopeptides of formula II would have to be prepared and screened to identify those that have an anti-bacterial effect does not constitute "undue experimentation," particularly in an art where the level of skill is high. In re Wands, 858 F.2d 731, 8 U.S.P.Q. 2d 1400, 1404 (Fed. Cir. 1988). In fact, the Federal Circuit has explicitly recognized that the need, and methodologies required, to carry out extensive synthesis and screening programs to locate bioactive molecules do not constitute undue experimentation. It is respectfully submitted that practitioners in the art related to the present application would be well-equipped to prepare glycopeptides of formula II, where R^{20} is $-R^a-W-R^h$ and where W is -S-C(=O)- and to screen such compounds to confirm their anti-bacterial activity. See also, Hybritech Inc. v. Monoclonal Antibodies Inc., 231 U.S.P.Q. 81, 84 (Fed. Cir. 1986) (evidence that screening methods used to identify characteristics [of monoclonal antibodies] were available to art convincing of enablement). Thus, the fact that a given claim may encompass a number of glycopeptides of formula II, where R^{20} is $-R^a-W-R^h$ and where W is -S-C(=O)- is not

dispositive of a lack of enablement, particularly in an art area in which the level of skill is very high and in which screening of large numbers of compounds is standard practice (Ex parte Forman, 230 U.S.P.Q. 546 (Bd. App. 1986)).

Therefore, given Applicant's disclosure, and the skill of the art worker in the relevant art area, Applicant submits that the preparation and screening of glycopeptides of formula (II), where R^{20} is $-R^a-W-R^h$ and where W is -S-C(=O)-, is well within the skill of the art and would not require undue experimentation.

Based on the remarks presented herein, it is respectfully submitted that the pending claims are in conformance with 35 U.S.C. § 112, first paragraph. Thus, withdrawal of the rejection of the claims under 35 U.S.C. §112, first paragraph, is respectfully requested.

Conclusion

Applicant respectfully submits that the claims (13, 14, 16, 17, and 20-23) are in condition for allowance and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney at (612) 359-3265 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743

Respectfully submitted,

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I hereby certify that this paper is being transmitted by facsimile to the U.S. Patent and Trademark Office on the date shown below.

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